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What are Bio-identical hormones?

Bio-identical hormones have the same chemical structure as hormones that are made by the human body. The key to natural or bio-identical versus synthetic is the molecular structure of the hormone. In order for a replacement hormone to fully replicate the function of hormones, which were originally naturally produced, and present in the human body, the chemical structure must exactly match the original.

Researchers have long held that there are significant differences between hormones that are natural to humans (bio-identical) and synthetic (including horse) preparations. Structural differences that exist between synthetic or animal and human hormones may be responsible for side effects that are experienced when non-bio-identical hormones are used for replacement therapy. It is the structure of the hormone, not the source, that is key. The term "bio-identical does not indicate the source of the hormone, but rather indicates that the chemical structure of the replacement hormone is identical to that of the hormone naturally found in the human body. Bio-identical hormones are chemically processed from precursors in yams or soy plants, yet they are identical to the hormones produced by the human; hence the term "bio-identical plant-derived hormone". These hormones are able to follow normal metabolic pathways so that essential active metabolites are formed in response to hormone replacement therapy. Synthetic- "patented," "conventional," "artificial" or "horse" hormones have been chemically altered, and are not identical in structure or activity to the naturally occurring hormones they are intended to replace.

Side chains are added to a natural substance to create a synthetic product that can he patented by a manufacturer. A patented drug can be profitable to mass-produce and therefore a drug company can afford to fund research as to the medication's use and effectiveness. However, bio-identical substances cannot be patented, so scientific studies are less numerous on these natural hormones, as medical research is frequently funded by drug companies.

Today's women prefer natural hormones. In a survey of a nationally representatives sample of 1,009 women aged 40 and older, 83% said they would prefer to use hormones that are similar to their own body's hormones. Bio-identical hormones include estrone (El), estradiol (E2), estriol (E3), progesterone, testosterone, dehydroepiandrosterone (DHEA), and pregnenolone.

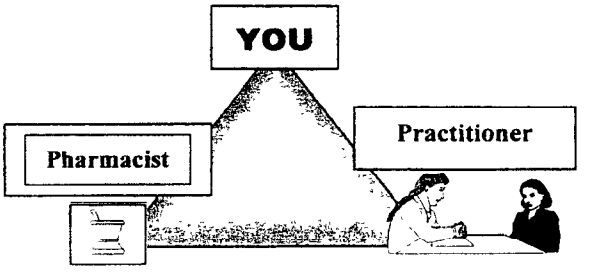
Hormone related symptoms or problems may occur <u>throughout the feminine life cycle.</u>

- ✓ *Dysmenorrhea (cramps)*
- ✓ *Premenstrual Syndrome (PMS)*
- ✓ *Infertility/Endometriosis*
- ✓ *Irregular menstrual periods*
- ✓ *Fibrocystic breasts*
- ✓ *Premenopausal symptoms*
- ✓ *Weight gain*
- ✓ *Mood swings*
- ✓ *Reduced libido*
- ✓ *Vaginal thinning/Dryness*
- ✓ *Painful intercourse*
- ✓ *Hot flashes*
- ✓ *Night sweats*
- ✓ *Depression*
- ✓ *Poor concentration/Memory lapses*
- ✓ *Insomnia/Disturbed sleep*
- ✓ *Heart disease/Arteriosclerosis*
- ✓ *Osteoporosis*

<u>Goals of Bio-Identical HRT</u>

- ❖ ***Alleviate the symptoms caused by the natural decrease in production of hormones by the body***
- ❖ ***Give the protective benefits which were originally provided by naturally occurring hormones***
- ❖ ***Re-estabish a hormonal balance***

Compounding pharmacists work together with patients and prescribers to provide customized bio-identical hormone replacement therapy in the best strength and dosage form to meet each individual's specific needs.



Natural bio-identical progesterone is commonly prescribed for perimenopausal women to counteract the condition known as "estrogen dominance". Perimenopause is the time between the onset of changes in hormonal secretions and menopause, and is characterized by fluctuating hormones. Estrogen dominance occurs when a woman produces smaller amounts of progesterone than normal relative to estrogen levels.

Jerilynn Prior, MD, of the University of British Columbia in Vancouver has presented evidence that progesterone can stimulate new bone formation in women with osteoporosis. This may indicate a role for progesterone use, alone or combined with estrogen which reduces bone loss, in improving Bone Mineral Density.[3]

The Postmenopausal Estrogen/Progestin Interventions (PEPI) Trial, a 3-year multicenter, randomized, double-blind, placebo-controlled study of 875 healthy postmenopausal women, confirmed that synthetic progestins partially negate the beneficial effects on cholesterol levels that result from taking estrogen. Natural progesterone, on the other hand, maintains the benefits of estrogen on cholesterol while minimizing the side effects associated with synthetic progestins such as medroxyprogesterone acetate.[4]

Mayo Clinic researchers surveyed 176 women faking natural micronized progesterone who had previously taken synthetic progestins to see if natural progesterone, when compared to synthetics, made a difference in the women's overall quality of life, menopausal symptoms, and satisfaction with HRT. After one to six months, the women reported an overall 34% increase in satisfaction on micronized progesterone compared to their previous HRT, reporting these improvements: 50% in hot flashes, 42% in depression, and 47% in anxiety. Micronized progesterone was also more effective in controlling breakthrough bleeding. Myagawa and Frank of Oregon Health Sciences University and USC School of Medicine compared medroxyprogesterone acetate (MPA) with natural progesterone as the progestin in HRT and studied the corresponding effect on coronary artery vasospasm. This research showed that progesterone plus estradiol protected against vasospasm, but MPA plus estradiol did not. In the past, the choice of MPA over progesterone has been based on familiarity and convenience. Based on the results presented here, formulations of natural progesterone would appear to offer the wiser alternative.[5]

Androgens, such as testosterone:

- enhance libido
- provide cardiovascular protection (lower cholesterol)
- enhance bone building (increase calcium retention)
- improve energy levels and mental alertness
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Recently, attention has turned to the addition of the androgens testosterone and dehydroepiandrosterone (DHEA) to ERT in order to alleviate recalcitrant menopausal symptoms and further protect against osteoporosis, loss of immune function, obesity and diabetes. ERT may represent incomplete preventive hormonal treatment in postmenopausal women because it does not directly address the declines in serum testosterone associated with hysterectomies and age-related gender-independent decline in DHEA and DHEA-sulfate. Additionally, ERT may cause relative ovarian and adrenal androgen deficiency, creating a rationale for concurrent physiologic androgen replacement.[6]

Every woman is unique. Therefore, it is a sensible approach for the patient to work together with health care professionals to customize hormone replacement therapy. Bio-identical HRT can be compounded in the needed strength and dosage form and administered via the most appropriate route to meet each woman's needs.

[1] *Proc* Soc *Exp Biol Med* 1998 Jan;217(1):6-16 and *Chem Res Toxicol* 1998 Sept;11(9):1105-11

[2] *Once A Month*, by Katharina Dalton, MD, (c) 1999, p. 246

[3] *Endocrine Reviews* 1990, 11(2): 386-398 and *Canadian Journal of Obstetrics/Gynecology & Women's Health Care* 1991, 3:178-84

[4] *JAMA*, Jan. 18, 1995, 273(3): 199-208

[5] *Nature Medicine*, 3(3):324-7 and *Journal of the American College of Cardiology*, March 1, 1997,pp. 671-5

[6] *Obstetrics & Gynecology* 1997 - 90(6):995-8

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BIO-IDENTICAL HORMONE REPLACEMENT

The three types of hormones typically prescribed for bio-identical hormone replacement therapy (BET) are estrogens, progesterone, and androgens. The precise components of each woman's therapy need to he determined after physical examination, medical history and laboratory testing are considered. Close monitoring is essential to ensure that appropriate dosage adjustments are made.

Estrogens:

- estrone (El), estradiol (E2), and estriol (E3) are often prescribed in combination to re-establish a normal physiologic balance
- relieve menopausal symptoms, including vaginal thinning and dryness
- may increase HDL "good" cholesterol and decrease LDL "bad" cholesterol
- help to decrease blood pressure and reduce plaque formation on the arterial walls
- reduce the risk of colorectal cancer
- may improve mood, energy levels, and sleep patterns
- may reduce the risk of developing or the severity of type *2* diabetes may improve memory and cognitive function
- reduce bone loss

The term estrogen" actually refers to a group of related hormones, each with a unique profile of activity. The three principle estrogens in humans are Estriol (E3), Estradiol (E2) and Estrone (El). The use of one or more of these hormones is referred to as Estrogen Replacement Therapy (ERT). These hormones are often prescribed in combination to re-establish a normal physiologic balance.

Estriol has been shown to be clinically effective for the treatment of menopausal symptoms as well as postmenopausal problems including vaginal atrophy, dryness, vaginal infections, painful intercourse, and various conditions of the urinary tract. Estriol is produced in very large amounts during pregnancy and may be protective against breast cancer. High levels of estriol are found in vegetarians and Asian women, who have a much lower incidence of breast cancer. Estradiol is the primary estrogen of ovarian origin and the major form of estrogen in pre-menopausal women. Estrone (made from the conversion of estradiol and androstenedione) is the primary estrogen in postmenopausal women.

Despite studies reporting the risks associated with sx'nthetic hormones. conjugated equine estrogens remain the most frequently prescribed form of ERT. Metabolites (breakdown products) of these svmithetic estrogens have been linked to the development of breast cancer.[1] In addition to treating menopausal symptoms ERT has been shown to he effective in decreasing the risk of Alzheimer's Disease and colorectal cancer. ERT also shows potential for treating patients with Multiple Sclerosis and arthritis.

Progesterone:

- is commonly prescribed for perimenopausal women to counteract "estrogen dominance"
- alone, or combined with estrogen, may improve Bone Mineral Density
- minimizes the risk of endometrial cancer in women who are receiving estrogen
- is preferred by women who had previously taken synthetic progestins, according to one Mayo Clinic study.
- may enhance the beneficial effect of estrogen on lipid and cholesterol profiles and exercise induced myocardial ischemia in post-menopausal women (in contrast to medroxyprogesterone acetate)

According to Katharina Dalton, M.D., approximately one in ten new mothers suffers from postpartum depression, or postnatal illness (PNI). "Unfortunately, women who have had PMS are prone to develop postnatal illness, but the good news is that PNI can be prevented by receiving progesterone immediately after delivery. Women who have had postpartum depression once have about a 68% chance of having it again after another pregnancy, but trials of prophylactic progesterone worldwide have shown that it is possible to reduce this recurrence rate to 7%.[2]